K033431

NOV 2 0 2003

510(k) SUMMARY

[As required by 21 CFR 807.87(h)]

Identification of Submitter

Submitter:	CTI PET Systems, Inc. 810 Innovation Drive Knoxville, TN 37932
Contact Person:	William Skremsky Senior Regulatory Affairs Specialist
Telephone No:	(865) 218-2522
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Date of preparation:	October 24, 2003

Identification of the Product

Device Proprietary Name:	LSO PET/CT HiRez and LSO PET/CT 16 HiRez
Common Name:	Combination Positron Emission Tomography (PET) and X-Ray Computed Tomography (CT)
Classification Name:	Emission Computed Tomography System per 21 CFR 892.1200

Marketed Devices to Which Equivalence is Claimed

Device	Manufacturer	510(k) Number
ECAT LSO PET/CT	CTI PET Systems (CPS)	K013504
ECAT LSO PET/CT 16	CTI PET Systems (CPS)	K023518

Device Description and Comparison to the Unmodified Device

The LSO PET/CT HiRez is a family of combined positron emission tomography (PET) and X-ray computed tomography (CT) scanners. These dual modality tomographs are modified versions of the ECAT LSO PET/CT (K013504) and ECAT LSO PET/CT 16 (K023518) and will utilize the same Siemens SOMATOM CT scanner components as their respective predicate PET/CT scanners. However, on this new family of CPS PET/CT HiRez systems, the ACCEL PET scanner electronics has been modified to appreciably increase PET count rate capability, with front-end acquisition electronics processing speed being significantly improved. The modified ACCEL PET scanner component will also incorporate a new version block detector utilizing a 13 by 13 LSO crystal matrix in place of the previously used 8 by 8 LSO crystal matrix which will provide a significant improvement in the spatial resolution of PET images. As with the predicate systems, 2D PET acquisition septa and PET transmission sources are not included in the modified LSO PET/CT HiRez systems. PET emission data are acquired only in 3D and PET attenuation correction map data are obtained from the CT. The PET and CT components of each system are contained within a unified housing similar to the predicate ECAT LSO PET/CT and ECAT LSO PET/CT 16 scanners to create an integrated PET, CT and combined PET/CT, tomographic imaging system.

The outward appearance of this family of modified PET/CT HiRez systems remains the same as the similarly configured preceding models. The LSO PET/CT HiRez gantry structure, patient handling system (PHS), advanced computational system (ACS 3) and workstation will be the same as those

used with the LSO PET/CT and ECAT LSO PET/CT 16 systems. Software used in these scanners will be the most recent version of the previously used PET/syngo software with minor changes to accommodate the revised PET acquisition electronics and modified crystal configuration detectors. User operating instructions have been revised accordingly.

The LSO PET/CT HiRez scanners are intended for use primarily as clinical, whole-body oncology machines with medium to high-end spiral CT performance and fast patient-throughput clinical PET performance. As on the predicate systems, the CT component will also enhance PET scans by allowing fast, essentially noise-free attenuation correction for PET studies, and by providing precise anatomical reference through fused PET and CT images. In addition, the LSO PET/CT HiRez scanners will retain mechanical isolation and independent functionality of the PET and CT scanning systems, thereby allowing for most standard CT and PET clinical diagnostic protocols to be available on these PET/CT systems.

The purpose of introducing this family of modified LSO PET/CT HiRez tomographic systems is to offer a series of PET/CT scanners having a varied range of CT performance combined with the fast patient throughput of the modified ACCEL PET, as an even higher performance alternative to the presently distributed ECAT LSO PET/CT and ECAT LSO PET/CT 16 PET/CT systems.

Intended Use

The LSO PET/CT HiRez and LSO PET/CT 16 HiRez tomographic scanner systems are combined positron emission tomography (PET) and X-ray computed tomography (CT) scanners. The LSO PET/CT HiRez and LSO PET/CT 16 HiRez scanners are intended to be utilized by appropriately trained health care professionals to 1) image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body; and 2) to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

The PET and the CT functions of this system can also be used in combination to provide high resolution, noise free CT attenuation correction maps for PET images and, additionally, utilized to produce fused CT and PET images, providing detailed anatomic and metabolic function information in a single image.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube and the simultaneous translation of the patient.)

Safety and Effectiveness

The LSO PET/CT HiRez and LSO PET/CT 16 HiRez tomographic scanner systems have been designed to comply with applicable industry safety standards for this type of medical equipment including the international standard IEC 60601-1, General Requirements for the Safety Electrical Medical Equipment. The CT component has been tested and meets the requirements of the applicable US Federal Performance Standards and regulations of 21CFR 1020.30 and 1020.33. The combined PET/CT system has been tested by CPS and found to meet its predetermined performance requirements.

Substantial Equivalence Determination

In the opinion of CPS, the ECAT LSO PET/CT 16 system utilizes the same scientific technology as the unmodified ECAT LSO PET/CT system and raises no new questions with regard to its safety and effectiveness. Therefore, we believe the modified ECAT LSO PET/CT 16 is substantially equivalent to the unmodified ECAT LSO PET/CT with respect to design, material and composition, energy source, and radiation safety characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2003

Mr. William Skremsky
Senior Regulatory Affairs Specialist
CPS Innovations
810 Innovation Drive
KNOXVILLE TN 37932

Re: K033431
Trade/Device Name: LSO PET/CT Hi Rez
and LSO PET/CT 16 Hi Rez
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed
tomography system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography
x-ray system
Regulatory Class: II
Product Code: 90 KPS and JAK
Dated: October 24, 2003
Received: November 4, 2003

Dear Mr. Skremsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033431

Device Name: LSO PET/CT Hi Rez and LSO PET/CT 16 HiRez

Indications for Use:

The LSO PET/CT Hi Rez and LSO PET/CT 16 HiRez tomographic scanner systems are combined positron emission tomography (PET) and X-ray computed tomography (CT) scanners. The LSO PET/CT Hi Rez and LSO PET/CT 16 HiRez scanners are intended to be utilized by appropriately trained health care professionals to 1) image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body; and 2) to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033431

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)